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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,200	02/06/2001	John Kisiday	01997/537001	8784

21559 7590 07/01/2002

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/778200

Applicant(s)

Kisiday et al

Examiner

Hoff

Group Art Unit

1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 2/6/01
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-18 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-18 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

The preliminary amendment of 10/15/01 to the specification has been entered.

Claims in the application are 1-18.

Restriction to one of the following inventions is required under 35

5 U.S.C. 121:

I. Claims 1-8, drawn to a macroscopic scaffold comprising amphiphilic peptides self-assembled to form a scaffold encapsulating cells, classified in class 435, subclass 289.1.

10 II. Claims 9, 10 and 14-18, drawn to methods of forming a macroscopic scaffold by incubating amphiphilic peptides and cells in an aqueous solution containing an iso-osmotic solute, and adding an electrolyte to the solution to cause self-assembly of the peptides and encapsulation of the cells, classified in class 435, subclass 177.

15 III. Claims 11 and 13-17, drawn to a method of regenerating tissue by administering to a mammal the macroscopic scaffold containing encapsulated cells, classified in class 424, subclass 423.

20 IV. Claim 12 and 13, drawn to a method of regenerating tissue involving administering to a mammal a solution containing amphiphilic peptides, cells and iso-osmotic solute, and after administration the peptides self-assembling to form a scaffold encapsulating the cells, classified in class 424, subclass 93.7.

25 The inventions are distinct, each from the other because:

The scaffold of invention I and administered in invention III can be produced other than as required by the methods of invention II. For example, the scaffold in inventions I and III can be formed without separate steps of incubating and adding electrolyte as required by invention II. The scaffold of inventions I and III can be formed by combining the peptides, cells, iso-osmotic solute and electrolyte in a single step to form the scaffold. The methods of scaffold formation of invention II can be carried out *in vitro* without forming the scaffold *in vivo* as in invention IV, and forming the scaffold in invention IV does not require incubating in a solution and then adding an electrolyte as in invention II. The scaffold of invention I and produced in invention II can have a use other than to regenerate tissue as in inventions III and IV. For example, the scaffold of invention I and produced in invention II can be used for cell culture *in vitro* to produce tissue, or to produce a peptide such as a cell growth factor that can be used to enhance cell growth *in vitro*. The methods tissue regeneration of inventions III and IV require different steps and are mutually exclusive methods, i.e. each method can be performed without carrying out the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application.

5 Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

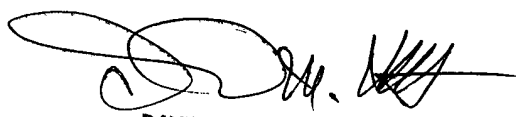
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on
10 Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the
15 examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this
20 application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 12657